

TRANSMITTAL LETTER TO THE UNITED STATES RECEIVING OFFICE

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| Date | 13 August 2002 |
| International Application No. | |
| Attorney Docket No. | 196002-2002 |

DT05 10/5/24864
13 AUG 2002

L Certification under 37 CFR 1.10 (if applicable)

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| EV 073700057US |
| Express Mail mailing number |

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| 13 August 2002 |
| Date of Deposit |

I hereby certify that the application/correspondence attached hereto is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

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| <i>Charles M. Simon</i> |
| Signature of person mailing correspondence |

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| <i>Charles M. Simon</i> |
| Typed or printed name of person mailing correspondence |

II. New International Application

| | | |
|-------|---|--|
| TITLE | REMOTELY ADJUSTABLE GASTRIC BANDING DEVICE AND METHOD | Earliest priority Date (Day/Month/Year) |
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13 August 2002

SCREENING DISCLOSURE INFORMATION: In order to assist in screening the accompanying international application for purposes of determining whether a license for foreign transmittal should and could be granted and for other purposes, the following information is supplied. (Note: check as many boxes as apply):

A. The invention disclosed was not made in the United States.

B. There is no prior U.S. application relating to this invention.

C. The following prior U.S. application(s) contain subject matter which is related to the invention disclosed in the attached international application. (Note: priority to these applications may or may not be claimed on form PCT/RO/101 (Request) and this listing does not constitute a claim for priority.)

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| Application no. | | Filed on | |
| Application no. | | Filed on | |
| Application no. | | Filed on | |
| Application no. | | Filed on | |

The present international application contains additional subject matter not found in the prior U.S. application(s) identified in paragraph C above. The additional subject matter is found on pages

D. DOES NOT ALTER MIGHT BE CONSIDERED TO ALTER the general nature of the invention in a manner which would require the U.S. application to have been made available for inspection by the appropriate defense agencies under 35 U.S.C. 181 and 37 CFR 5.1. See 37 CFR 5.15.

III. A response to an Invitation from the RO/US. The following document(s) is(are) enclosed:

A. A Request for An Extension of Time to File a Response.

B. A Power of Attorney (General or Regular)

C. Replacement Pages

| | | | |
|-------|-----------------------------|-------|-----------------|
| pages | of the request (PCT/RO/101) | pages | of the figures |
| pages | of the description | pages | of the abstract |
| pages | of the claims | | |

D. Submission of Priority Documents

| | |
|-------------------|-------------------|
| Priority document | Priority document |
|-------------------|-------------------|

E. Fees as specified on attached Fee Calculation sheet form PCT/RO/101 annex

IV. A Request for Rectification under PCT 91 A Petition A Sequence Listing Diskette

V. Other (please specify): Check in the amount of \$1,787.00

| | |
|--|-------------------------------------|
| <input type="checkbox"/> Applicant | Darren M. Simon |
| | Typed name of signer |
| <input checked="" type="checkbox"/> Attorney/Agent (Reg. No. 47,946) | |
| <input type="checkbox"/> Common Representative | <i>Darren M. Simon</i> Signature |

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty

receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired)(12 characters maximum) 196002-2002

**Box No. I TITLE OF INVENTION
REMOTELY ADJUSTABLE GASTRIC BANDING DEVICE AND METHOD**

Box No. II APPLICANT This person is also inventor.

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

Telephone No.

Facsimile No.

Teleprinter No.

Applicant's Registration No. with the Office

**INAMED MEDICAL PRODUCTS CORPORATION
5540 Ekwill Street
Santa Barbara, CA 93111
United States of America**

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant all designated states all designated states except the United States of America the United States of America only the states indicated in the Supplemental Box

Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

This person is:

applicant only

applicant and inventor

inventor only (if this check-box is marked, do not fill in below.)

Applicant's registration No. with the Office:

State (that is, country) of nationality:

US

State (that is, country) of residence:

US

This person is applicant all designated states all designated states except the United States of America the United States of America only the states indicated in the Supplemental Box

Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as:

agent

common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)

Telephone No. (212) 588-0800

**VAN BUSKIRK, Tedd W.
SIMON, Darren M.
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151
United States of America**

Facsimile No. (212) 588-0500

Teleprinter No.

Agent's registration No. with the Office
46,282 and 47,946

Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.

Box No. V

SIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, MZ Mozambique, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZM Zambia, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- EP European Patent: AT Austria, BE Belgium, BG Bulgaria, CH & LI Switzerland and Liechtenstein, CY Cyprus; CZ Czech Republic, DE Germany, DK Denmark, EE Estonia, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, SK Slovakia, TR Turkey and any other State which is a Contracting State of the European Patent Convention and of the PCT
- OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GQ Equatorial Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (*if other kind of protection or treatment desired, specify on dotted line*).

National Patent (if other kind of protection or treatment desired, specify on dotted line).

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| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> GH Ghana..... | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> AG Antigua and Barbuda | <input checked="" type="checkbox"/> GM Gambia..... | <input checked="" type="checkbox"/> MZ Mozambique |
| <input checked="" type="checkbox"/> AL Albania..... | <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> AM Armenia..... | <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> AT Austria..... | <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> OM Oman |
| <input checked="" type="checkbox"/> AU Australia..... | <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> PH Philippines |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> IS Iceland | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> BG Bulgaria..... | <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> BR Brazil..... | <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> BZ Belize | <input checked="" type="checkbox"/> KR Republic of Korea | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> KZ Kazakhstan | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> CH & LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> LC Saint Lucia | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> LK Sri Lanka | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> CO Colombia | <input checked="" type="checkbox"/> LR Liberia | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> CR Costa Rica | <input checked="" type="checkbox"/> LS Lesotho | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> LT Lithuania | <input checked="" type="checkbox"/> TN Tunisia |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> LU Luxembourg | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> LV Latvia | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> MA Morocco | <input checked="" type="checkbox"/> TZ United Republic of Tanzania |
| <input checked="" type="checkbox"/> DM Dominica | <input checked="" type="checkbox"/> MD Republic of Moldova | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> DZ Algeria | <input checked="" type="checkbox"/> MG Madagascar | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> EC Ecuador | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> MN Mongolia | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> MW Malawi | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> FI Finland | | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> GB United Kingdom | | <input checked="" type="checkbox"/> ZA South Africa |
| <input checked="" type="checkbox"/> GD Grenada | | <input checked="" type="checkbox"/> ZM Zambia |
| <input checked="" type="checkbox"/> GE Georgia | | <input checked="" type="checkbox"/> ZW Zimbabwe |

Check-box reserved for designating States which have become party to the PCT after issuance of this sheet:

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| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)

| | | | | |
|---|--|---|--|--|
| Box No. VI PRIORITY CLAIM | | | | |
| The priority of the following earlier application(s) is hereby claimed: | | | | |
| Filing date of earlier application (day/month/year) | Number Of earlier applications | Where earlier application is: | | |
| | | national application: country or Member of WTO | Regional application: * Regional Office | international application: receiving Office |
| Item (1) | | | | |
| Item (2) | | | | |
| Item (3) | | | | |
| Item (4) | | | | |
| Item (5) | | | | |
| <input type="checkbox"/> Further priority claims are indicated in the Supplemental Box. | | | | |
| <p>The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) <i>only if the earlier application was filed with the Office which for the purposes of this international application is the receiving Office</i>) identified above as:</p> <p><input type="checkbox"/> all items <input type="checkbox"/> item (1) <input type="checkbox"/> item (2) <input type="checkbox"/> item (3) <input type="checkbox"/> item (4) <input type="checkbox"/> item (5) <input type="checkbox"/> other, see Supplemental Box</p> <p>* Where the earlier application is an ARIPO application, indicate at least one country party to the Paris Convention for the Protection of Industrial Property or one Member of the World Trade Organization for which that earlier application was filed (Rule 4.10(b)(ii)):</p> | | | | |
| Box No. VII INTERNATIONAL SEARCHING AUTHORITY | | | | |
| <p>Choice of International Searching Authority (ISA) (If two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</p> <p>ISA/ US</p> <p>Request to use results of earlier search; reference to that search (If an earlier search has been carried out by or requested from the International Searching Authority):</p> | | | | |
| Date (day/month/year) | Number | Country (or regional Office) | | |
| Box No. VIII DECLARATIONS | | | | |
| The following declarations are contained in Boxes Nos. VIII (i) to (v) (mark the applicable | | | | Number of declarations |
| <input type="checkbox"/> Box No. VIII (i) | Declaration as to the identity of the inventor | : | | |
| <input type="checkbox"/> Box No. VIII (ii) | Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent | : | | |
| <input type="checkbox"/> Box No. VIII (iii) | Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application | : | | |
| <input type="checkbox"/> Box No. VIII (vi) | * Declaration of inventorship (only for the purposes of the designation of the United States of America) | : | | |
| <input type="checkbox"/> Box No. VIII (v) | Declaration as to non-prejudicial disclosures or exceptions to lack of novelty | : | | |

| Box No. IX CHECK LIST; LANGUAGE OF FILING | | Number of items | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|----------|-----------------|--|---|---|---|---|---|--------|---|---|----------|---|---|----------|---|---|------------------------------------|----------|-----------|---|--|---|-----------------------------------|--|-------------|--|--|--|---|--|--|---|--|--|---|--|--|-----------|--|--|---|--|---|--|--|
| <p>This international application contains:</p> <p>(a) the following number of sheets in paper form:</p> <table> <tr><td>request (including declaration sheets)</td><td>:</td><td>4</td></tr> <tr><td>description (excluding sequence listing part)</td><td>:</td><td>8</td></tr> <tr><td>claims</td><td>:</td><td>4</td></tr> <tr><td>abstract</td><td>:</td><td>1</td></tr> <tr><td>drawings</td><td>:</td><td>2</td></tr> <tr><td>Sub-Total number of sheets:</td><td>:</td><td>19</td></tr> <tr><td colspan="2"> sequence listing part of description (actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below)</td><td>:</td></tr> <tr><td colspan="2"> Total number of sheets</td><td>: 19</td></tr> <tr><td colspan="2"> (b) sequence listing part of description filed in computer readable form</td><td></td></tr> <tr><td colspan="2">(i) <input type="checkbox"/> only (under Section 801(a)(i))</td><td></td></tr> <tr><td colspan="2">(ii) <input type="checkbox"/> in addition to being filed in paper form (under Section 801(a)(ii))</td><td></td></tr> <tr><td colspan="2"> Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained (additional copies to be indicated under item 9(ii) in right column):</td><td></td></tr> <tr><td colspan="2"></td><td></td></tr> <tr><td colspan="2"> Figure of the drawings which should accompany the abstract:</td><td>3</td></tr> <tr><td colspan="2"> Language of filing of the international application:</td><td>English</td></tr> </table> | | | request (including declaration sheets) | : | 4 | description (excluding sequence listing part) | : | 8 | claims | : | 4 | abstract | : | 1 | drawings | : | 2 | Sub-Total number of sheets: | : | 19 | sequence listing part of description (actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below) | | : | Total number of sheets | | : 19 | (b) sequence listing part of description filed in computer readable form | | | (i) <input type="checkbox"/> only (under Section 801(a)(i)) | | | (ii) <input type="checkbox"/> in addition to being filed in paper form (under Section 801(a)(ii)) | | | Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained (additional copies to be indicated under item 9(ii) in right column): | | | | | | Figure of the drawings which should accompany the abstract: | | 3 | Language of filing of the international application: | |
| request (including declaration sheets) | : | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| description (excluding sequence listing part) | : | 8 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| claims | : | 4 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| abstract | : | 1 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| drawings | : | 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Sub-Total number of sheets: | : | 19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| sequence listing part of description (actual number of sheets if filed in paper form, whether or not also filed in computer readable form; see (b) below) | | : | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Total number of sheets | | : 19 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (b) sequence listing part of description filed in computer readable form | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (i) <input type="checkbox"/> only (under Section 801(a)(i)) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| (ii) <input type="checkbox"/> in addition to being filed in paper form (under Section 801(a)(ii)) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Type and number of carriers (diskette, CD-ROM, CD-R or other) on which the sequence listing part is contained (additional copies to be indicated under item 9(ii) in right column): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| Figure of the drawings which should accompany the abstract: | | 3 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Language of filing of the international application: | | English | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| **Box No. X SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE** *Next to each signature, indicate the name of the person signing and the capacity in which the person signed (if such capacity is not obvious from reading the request).* Darren M. Simon | | |

| For receiving Office use only | | |
|---|------|--|
| 1. Date of actual receipt of the purported international application: | | 2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received: |
| 3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application: | | |
| 4. Date of timely receipt of the required corrections under PCT Article 11 (2): | | |
| 5. International Searching Authority (if two or more are competent): | ISA/ | |
| 6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid. | | |

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|---|--|
| Date of receipt of the record copy by the International Bureau: | |

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FEE CALCULATION
Annex to the Request

Applicant's or agent's
file reference 196002-2002

International application no.

Date stamp of the receiving Office

Applicant INAMED MEDICAL PRODUCTS CORPORATION

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE \$240.00 T

2. SEARCH FEE \$700.00 S

International search to be carried out by US

(If two or more International Searching Authorities are competent to carry out the international search, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

Where item (b) of Box No. IX applies, enter Sub-Total number of sheets

Where item (b) of Box No. IX does not apply, enter Total number of sheets } 19

b1 first 30 sheets \$ 407.00 b1

b2 _____ x \$9.00 = 000.00 b2

number of sheets in
excess of 30 fee per sheet

b3 additional component (only if sequence listing part of description
is filed in computer readable form under Section 801(a)(i), or
both in that form and on paper, under Section 801(a)(ii)):

400 x = b3
fee per sheet

Add amounts entered at b1, b2 and b3 enter total at B 407.00 B

Designation Fees

The international application contains designations.

5 X \$88.00 = 440.00 D

Number of designation fees
payable (maximum 5) amount of designation fee

Add amounts entered at B and D and enter total at I \$847.00 I

(Applicants from certain States are entitled to a reduction of 75% of the
international fee. Where the applicant is (or all applicants are) so entitled, the
total to be entered at I is 25% of the sum of the amounts entered at B and D.)

4. FEE FOR PRIORITY DOCUMENT (if applicable) 0.00 P

5. TOTAL FEES PAYABLE \$1,787.00

Add amounts entered at T, S, I and P, and enter total in the TOTAL box TOTAL

The designation fees are not paid at this time

MODE OF PAYMENT

Authorization to charge postal money order cash coupons
deposit account (see below)

cheque bank draft revenue stamps other (specify):

AUTHORIZATION TO CHARGE (OR CREDIT) DEPOSIT ACCOUNT
(This mode of payment may not be available at all receiving Offices)

Receiving Office: RO/US

Authorization to charge the total fees indicated above.

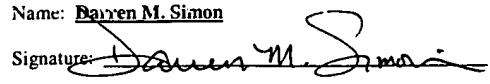
Deposit Account No.: 50-0320

(This check-box may be marked only if the conditions for deposit accounts of the
receiving Office so permit) Authorization to charge any deficiency or credit any
overpayment in the total fees indicated above.

Date: 13 August 2002

Authorization to charge the fee for priority document.

Name: Darren M. Simon

Signature: 

REMOTELY ADJUSTABLE GASTRIC BANDING DEVICE AND METHOD**BACKGROUND OF THE INVENTION****5 Field of the Invention**

The present invention relates generally to an apparatus for remotely adjusting the volume in the inflatable portion of a surgically implanted gastric band encircling the stomach. A method for treating morbid obesity utilizing a remotely adjustable gastric banding device is also disclosed.

10

Description of the Related Art

A belt-like gastric band for encircling the stomach to control morbid obesity is disclosed by Vincent in U.S. Pat. 5,601,604, incorporated herein by reference. The band comprises a belt that can be passed around the stomach and locked into an encircling position in order to create a stoma opening within the stomach. An adjustable portion of the band comprises an inflatable member which permits fine adjustment of the stoma opening after the stoma is created by locking the band in place.

The gastric banding procedure may involve placement of a calibrating apparatus in the stomach to position the stoma and size the pouch created above the stoma. The gastric band is fastened in position about the stomach to prevent slippage, usually by gastro-gastric sutures.

The stoma opening may be adjusted by injecting or withdrawing a fluid into or from an inflatable member, which is preferably coextensive with a portion of the inner stomach-contacting surface of the band. The means for injecting the fluid into the inflatable member usually comprises a fill port located beneath the skin that can be accessed extracorporeally by transdermal injection. Thus, following implantation, the gastric band can be adjusted to enlarge or reduce the stoma as required.

A potential disadvantage of prior art gastric bands is the difficulty in finely adjusting the stoma created by the implanted band. For example, the fill port located beneath the skin can be difficult to locate precisely. In addition, the fill procedure requires an invasive transdermal injection to adjust the band. Hence,

repeated adjustments may be painful or worrisome to the patient. Moreover, exposure to x-rays may be required to facilitate location of the port. It would therefore be desirable to provide a band having an inflatable member that can be easily, precisely, and readily adjusted remotely, without the need to undergo an invasive procedure or radiographic exposure.

To address this problem, several prior art remote control gastric banding devices have been proposed. Klaiber et al. (U.S. Pat. 5,938,669) discloses a radio controlled gastric band adjusted by means of an electric pump and a balancing reservoir. Forsell (U.S. Pat. 6,210,347) discloses a remotely controlled and powered gastric band adjusted by a motorized mechanical or hydraulic means. Each of these proposed devices operates by pumping fluid to or from the gastric band. Unfortunately, because of their energy requirements, these devices pose problems for practical use. These devices are also not suitable for use with existing gastric banding systems, such as that disclosed by Vincent.

Recent developments in implantable drug delivery devices have shown that small, reliable, and energy-efficient implantable devices are feasible. Drug delivery devices currently exist in which drugs are administered periodically or continuously to a patient having an implanted device by applying pressure from a pressurized reservoir and opening an outlet valve to allow a pressure differential to cause a flow of the drug. For example, Malamud et al. (U.S. Patent 5,928,195) discloses a remotely controlled drug delivery device suitable for implantation in a body cavity. A pressurized gas chamber presses upon a drug storage chamber thereby administering a dose of the drug when a valve is remotely opened.

Similarly, Arzbaecher (U.S. Patent 5,607,418) discloses an implantable drug apparatus having nested deformable chambers with the outer chamber being pressurized. The pressure from the outer pressurized chamber forces the drug from a reservoir chamber into an inner dispensing chamber. A remotely controlled valve is used to administer a dose of the drug from the dispensing chamber. Further, Haller et al. (U.S. Patent 6,203,523) discloses an implantable drug infusion device having a flow regulating mechanism that permits the flow rate to be independent of reservoir pressure. Some of the tradeoffs between "passive" (pressurized reservoir-based) devices and "active" (pump-based) devices are discussed in Haller, the disclosure of which is incorporated herein by reference.

OBJECTS OF THE INVENTION

The foregoing demonstrates a need for a practical, accurate and easy means of remotely adjusting an implanted gastric band.

5 It is therefore an object of the present invention to provide a practical, accurate and efficient means for remotely adjusting an implanted gastric band.

It is another an object of the present invention to remotely adjust an implanted gastric band having an inflatable member.

10 It is yet another object of the invention to provide a remote control means suitable for use with existing gastric banding devices and technology.

Still another an object of the present invention is to minimize device complexity for an implanted remotely adjustable gastric banding device to ensure maximum device longevity/durability, in light of the fact that repair would require additional surgery.

15 Various other objects, advantages and features of the present invention will become readily apparent from the ensuing detailed description and the novel features will be particularly pointed out in the appended claims.

SUMMARY OF THE INVENTION

20 The present invention applies recent developments in implantable drug delivery device technology to the field of gastric banding.

A preferred embodiment of the invention provides a gastric banding device for treatment of morbid obesity. The device has a gastric band suited for laparoscopic placement around the stomach of a patient to form an adjustable stoma opening. The gastric band has an inflatable chamber for adjusting the inner circumference of the band. The inflatable chamber is preferably substantially coextensive with an inner stomach-facing surface of the gastric band. The inflatable member does not wrinkle or fold when adjusted, thereby presenting a substantially smooth contour along the inner circumference. A fluid-filled pressurized reservoir provides a source of fluid to inflate the inflation chamber of the gastric band. First and second valves control the flow between the pressurized reservoir, the inflatable chamber, and an unpressurized or negatively pressurized outlet. A controller is used to control the valves, thereby regulating the volume change in the inflatable chamber

to adjust the inner circumference of the band. The controller is remotely controllable from outside of the patient.

Other aspects of the invention include a remote control for remotely transmitting control signals to the controller, a receiver for receiving control signals from the remote control, and a power source for providing power to the controller and the valves. The power source may be an induction coil. The power source may also be a battery or capacitor charged by a piezoelectric device which converts body motion into electrical energy.

In a method according to the invention, a remotely adjustable gastric banding system may be used for the treatment of obesity. The method comprises the steps of implanting a gastric band, preferably laparoscopically, around the stomach of the patient to create a stoma; remotely transmitting control signals from outside of the patient to a controller of the implanted gastric banding device; and actuating a first valve, between a pressurized reservoir and an inflatable chamber, and/or a second valve, between the inflatable chamber and an outlet, on the basis of the control signals received by the controller to increase or decrease the fluid volume in the inflatable chamber, thereby adjusting the inner circumference of the band to adjust the stoma.

20

BRIEF DESCRIPTION OF THE DRAWINGS

The following detailed description given by way of example, but not intended to limit the invention solely to the specific embodiments described, may best be understood in conjunction with the accompanying drawings in which:

25 Figure 1 is a perspective view of a laparoscopically implantable gastric band, which may be used in the present invention, fastened in an encircling position and partially inflated;

Figure 2 is a side view of the gastric band shown in Figure 1; and

Figure 3 is a schematic diagram showing a remotely controlled fluid distribution system for a gastric band according to the present invention.

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DETAILED DESCRIPTION OF CERTAIN PREFERRED EMBODIMENTS

The present invention combines the implantable drug delivery device technology discussed above with gastric banding technology. The preferred

embodiments of the apparatus and method according to the present invention will be described with reference to the accompanying drawings.

Referring to Figure 1, a gastric band for use with the present invention is disclosed in Vincent (U.S. Patent 5,601,604). This compatible gastric band, indicated as reference numeral 10, has a body portion 11 with an inner stomach-facing surface 15. The body portion 11 has a head end 12 and a tail end or "belt" 13. A fill tube 14, which is generally a tube having a single lumen coextensive therewith, is in fluid communication with an inflatable chamber 16 on the inner surface 15 of the band body 11. Preferably, the inflatable portion 16 is substantially coextensive with the inner surface 15 of the body portion 11. The central lumen of the fill tube 14 is in fluid communication with inflatable chamber 16. The head end 12 of the body portion 11 has a "buckle" 19 through which the tail end of "belt" 13 is inserted and locked in place in use. Head end 12 may be provided with a pull tab 18 for use in locking the band in place about the stomach.

In use, the gastric band is placed in an encircling position around the stomach and locked in place as shown in Figure 2. (In Figure 2, the stomach is omitted for clarity.) This is accomplished by introducing the gastric band 10 through a laparoscopic cannula (not shown) in a patient's abdominal cavity. Laparoscopic placement consists of blunt dissection below the gastro-esophageal junction followed by placement of the band. The end of the fill tube 14 is passed through the dissected path around the upper stomach, and the tail end or belt 13 is passed through buckle 19, so that the belt and buckle lock in place. A laparoscopic closure tool, such as that disclosed by Coe and Vincent in U.S. Pat. 5,658,298, incorporated herein by reference, may be used. Hence, with the gastric band affixed in an encircling position around the stomach, a new stoma (opening) is created within the stomach. After the band is secured in position, the size of the stoma may be adjusted by adding fluid to or withdrawing fluid from the inflatable member 16 to bring the stoma opening to the desired size. The inflatable member or chamber 16 is preferably coextensive with the inner stomach-facing surface 15 of the band between the head end 12 and the tail end 13. The interior of the adjustable chamber 16 is in fluid communication with a fluid reservoir (not shown) by means of the central lumen of the fill tube 14, as with prior art adjustable gastric bands. The inflatable member 16 is gradually inflated or deflated with saline or other biologically

compatible fluid via the fluid reservoir such that the inflatable member 16 presses on and constricts the stomach wall or other tissue underlying the band. This results in the decrease or increase of the size of the stomach opening directly inside the encircling band.

5 Figure 3 is a schematic diagram depicting a remotely adjustable gastric band 100 constructed in accordance with the present invention. In Figure 3, the pressure in the inflatable member 16 of the remote gastric banding system 100 is represented by the band inflation pressure P2. Pressure P2 is regulated by an inlet valve 31 and an outlet valve 32. Pressurized reservoir 20, having a pressure P1, is
10 connected to the inflatable chamber 16 through inlet valve 31 and tube 21, which corresponds to fill tube 14 in Figure 2. Pressurized reservoir 20 is analogous to the pressurized reservoirs discussed above in relation to implantable drug delivery devices. This reservoir may be connected to the fill tube 21 as shown, or it may be incorporated into the body 11 of the band itself, e.g. on the outer surface, opposite
15 the inner stomach-facing surface 15, and communicate directly with inflatable chamber 16 through inlet valve 21. Inflatable member 16 is also connected to outlet 23, having a pressure P3, through tube 22 and valve 32. Outlet 23 may be either a separate waste reservoir as shown in Figure 3 or the peritoneal cavity of the patient's body. When outlet 23 is a waste reservoir, P3 may be negative. Where pressure
20 outlet 23 is the patient's peritoneal cavity, P3 will be at ambient pressure within the body.

In the present invention, the pressure relationship between reservoir 20, inflatable member 16 and outlet 23 is initially represented by the formula $P1 > P2 > P3$. Hence, valve 31 may be used to increase the pressure P2 up to a maximum pressure of $P2=P1$, thereby inflating inflatable member 16. Similarly, valve 32 may be used to decrease the pressure P2 down to a minimum of $P2=P3$, thereby deflating inflatable member 16. Thus, by actuating valves 31 and 32, the fluid volume in the inflatable member 16 may be regulated, thereby adjusting the size of the stoma formed by the gastric band.

25 30 In the present invention, valves 31 and 32 are controlled by a controller 41. The valves are preferably controlled in accordance with externally transmitted signals (not shown) received by a receiver 42 but may ultimately be controlled by any control system, including internal, mechanical, wired, or the like.

The signals are preferably radio frequency (RF) signals transmitted by a remote control device 40 located external to the implanted gastric banding system. Power may be supplied to the receiver, the controller, and/or the valves either from an implanted power source 43 or from an induction coil 43 that receives power from a 5 concentric coil external to the body, as described for instance for hearing aids in Baumann et al. (U.S. Patent 5,279,292), which is hereby incorporated by reference.

The entirety of the remote gastric banding system 100 shown in Figure 3 may be laparoscopically implanted in the patient. Subsequent adjustment of the band can be simply, quickly, and painlessly performed using a remote control 10 device to remotely inflate/deflate the inflatable portion 16 of the band. The entire system 100 may be removed from the patient if necessary. No permanent anatomical changes should be anticipated.

The remote control device 40 can be in the form of a typical television remote control, a personal computer interfaced device, or any other 15 format. A unique identification code may be assigned to each remotely adjustable gastric band, so that access to and control of the device is restricted. This code may be a PIN code and may also act to prevent accidental adjustment of the band.

The system may be pressurized using a saline solution, or any other biocompatible fluid. If desired, a concentrated saline solution may be used as the 20 inflation medium, thereby allowing water from the patient's body to diffuse into the inflatable member 16 over time and further inflate the band. After repeated adjustments the reservoir 20 may be refilled through an access port (not shown) or replaced altogether. As a backup and safety measure, the system may also allow for inflation/deflation of inflatable member 16 by transdermal injection through a fill 25 port (not shown) as in prior art gastric banding devices.

Because this system uses a pressurized reservoir rather than a mechanical pressurization means (*i.e.* a pump or screw), the present system is more energy-efficient than those disclosed in the existing remote-controlled adjustable gastric band systems of Klaiber or Forsell (U.S. Patents 5,938,669 and 6,210,347). 30 Power is only required when operating the valves 31 and/or 32, and then only for relatively short time intervals.

Alternative embodiments of the present invention may include means for measuring fluid flow through the valves 31 and/or 32, such as a mass flowmeter,

to ensure accuracy in adjusting the stoma when inflatable member 16 is inflated or deflated. Also, the controller 41 may be positioned external to the body. An alternate gastric band design might also be used, provided that the inflation medium remains a fluid.

5 A further embodiment of the present invention is a method of treating obesity using the remotely adjustable gastric banding system disclosed herein. The method includes implanting a gastric band, preferably laparoscopically, around the stomach of the patient to create a stoma; remotely transmitting control signals from outside of the patient to controller 41 of the gastric banding device inside of the
10 patient; and opening and closing valve 31, between pressurized reservoir 20 and inflatable chamber 16, and/or valve 32, between the inflatable chamber and outlet 23, on the basis of the control signals received by controller 23 to increase or decrease the pressure in the inflatable chamber, thereby adjusting the inner circumference of the band to adjust the stoma size.

15 Although the invention has been particularly shown and described with reference to certain preferred embodiments, it will be readily appreciated by those of ordinary skill in the art that various changes and modifications may be made therein, without departing from the spirit and scope of the invention. It is intended that the claims be interpreted as including the foregoing as well as various
20 other such changes and modifications.

WHAT IS CLAIMED IS:

1. A gastric banding apparatus for treatment of obesity in a patient, comprising:
 - a gastric band suitable for laparoscopic placement around the stomach of the patient to create a stoma; said gastric band having an inflatable chamber for adjusting an inner circumference of the band;
 - 5 a pressurized fluid reservoir for providing fluid to inflate said inflation chamber;
 - a first valve between said pressurized fluid reservoir and said inflatable chamber;
 - 10 a second valve between said inflatable chamber and an outlet;
 - a controller for actuating said first and second valves thereby increasing or decreasing the fluid volume in said inflatable chamber to adjust the inner circumference of the band; said controller being remotely controllable from outside of the patient.
2. The gastric banding apparatus according to claim 1, further comprising a remote control for remotely transmitting control signals to the controller.
- 20 3. The gastric banding apparatus according to claim 1, further comprising a receiver for receiving control signals wherein said controller actuates said first and second valves in response to the received signals.
4. The gastric banding apparatus according to claim 1, further comprising a power source for providing power to said controller, said first valve, and said second valve.
- 25 5. The gastric banding apparatus according to claim 4, wherein said power source is an induction coil.
- 30 6. The gastric banding apparatus according to claim 4, wherein said power source is a battery.

7. The gastric banding apparatus according to claim 4, wherein said power source is a capacitor.

8. The gastric banding apparatus according to claim 7, wherein said 5 capacitor is piezo-electrically charged.

9. The gastric banding apparatus according to claim 1, wherein said outlet is the peritoneal cavity of the patient.

10 10. The gastric banding apparatus according to claim 1, wherein said outlet is a waste reservoir.

11. The gastric banding apparatus according to claim 10, wherein said waste reservoir is negatively pressurized.

15 12. The gastric banding apparatus according to claim 1, wherein said inflatable chamber is substantially coextensive with an inner stomach-facing surface of said gastric band.

20 13. The gastric banding apparatus according to claim 12, wherein said inflatable chamber does not wrinkle or fold when adjusted, thereby presenting a substantially smooth contour along said inner circumference.

14. The gastric banding apparatus according to claim 1, wherein said 25 gastric band forms a smoothly surfaced circle.

15. The gastric banding apparatus according to claim 14, wherein said gastric band is lockable in said smoothly surfaced circle.

30 16. The gastric banding apparatus according to claim 1, wherein the fluid in said pressurized fluid reservoir is saline.

17. A method of treating obesity in a patient, comprising the steps of:

implanting a gastric banding device around the stomach of the patient to create a stoma; said gastric banding device having an inflatable chamber;

remotely transmitting control signals from outside of the patient to a controller of the gastric banding device inside of the patient; and

5 actuating a first valve, between a pressurized fluid reservoir and said inflatable chamber, or a second valve, between said inflatable chamber and an outlet, on the basis of the control signals received by the controller to increase or decrease the fluid volume in said inflatable chamber, thereby adjusting an inner circumference of the band.

10

18. The method according to claim 17, wherein the control signals are remotely transmitted using a remote control.

19. The method according to claim 17, wherein the controller has a
15 receiver for receiving the control signals.

20. The method according to claim 17, wherein said inflatable chamber is substantially coextensive with an inner stomach-facing surface of said gastric band.

20 21. The method according to claim 17, wherein said gastric band forms a smoothly surfaced circle.

22. A gastric banding apparatus for treatment of obesity in a patient, comprising:

25 a laparoscopically implantable gastric band having an inflatable member for adjusting an inner circumference of the band;

a reservoir for providing pressurized fluid to inflate said inflation member;

a valve between said reservoir and said inflatable member;

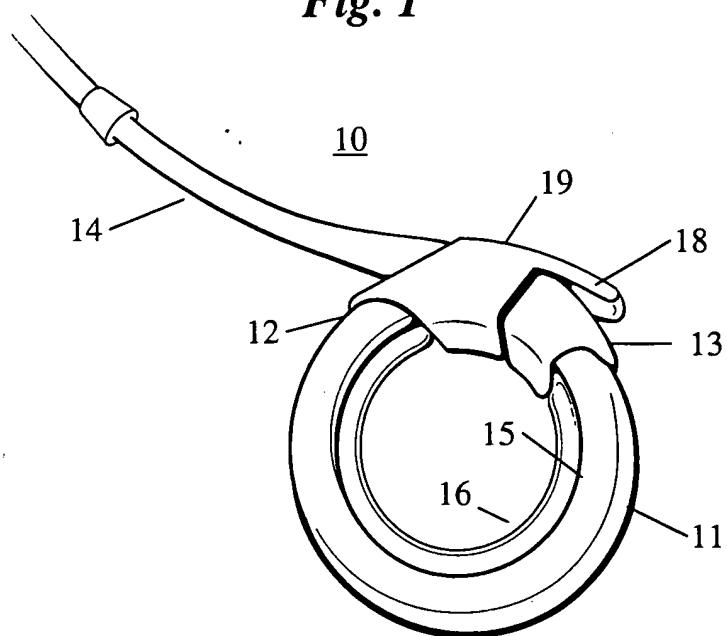
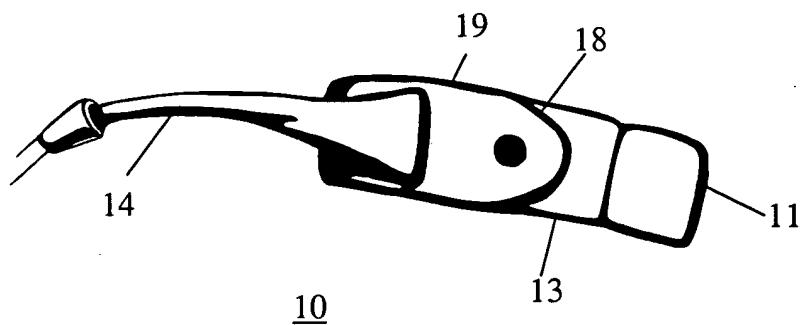
30 a controller for opening and closing said valve thereby increasing the volume of said inflatable member to decrease the inner circumference of the band.

23. The gastric banding apparatus according to claim 22, further comprising a valve between said inflatable member and an outlet; said controller opening and closing said valve between said inflatable member and an outlet thereby decreasing the volume of said inflatable member to increase the inner circumference
5 of the band.

24. The gastric banding apparatus according to claim 23, wherein the controller is remotely controllable from outside of the patient.

ABSTRACT OF THE DISCLOSURE

A remotely controllable gastric banding device suitable for laparoscopic placement around the stomach of a patient for the treatment of obesity is disclosed. The device comprises a gastric band having an inflatable chamber for adjusting the inner circumference of the band, a pressurized reservoir with a valve for providing fluid to inflate the inflation chamber, a valve for releasing fluid from the inflatable chamber, and a controller for controlling the valves. The controller is remotely controllable from outside of the patient to regulate fluid flow to or from the inflatable chamber, thereby adjusting the inner circumference of the band.

Fig. 1*Fig. 2*

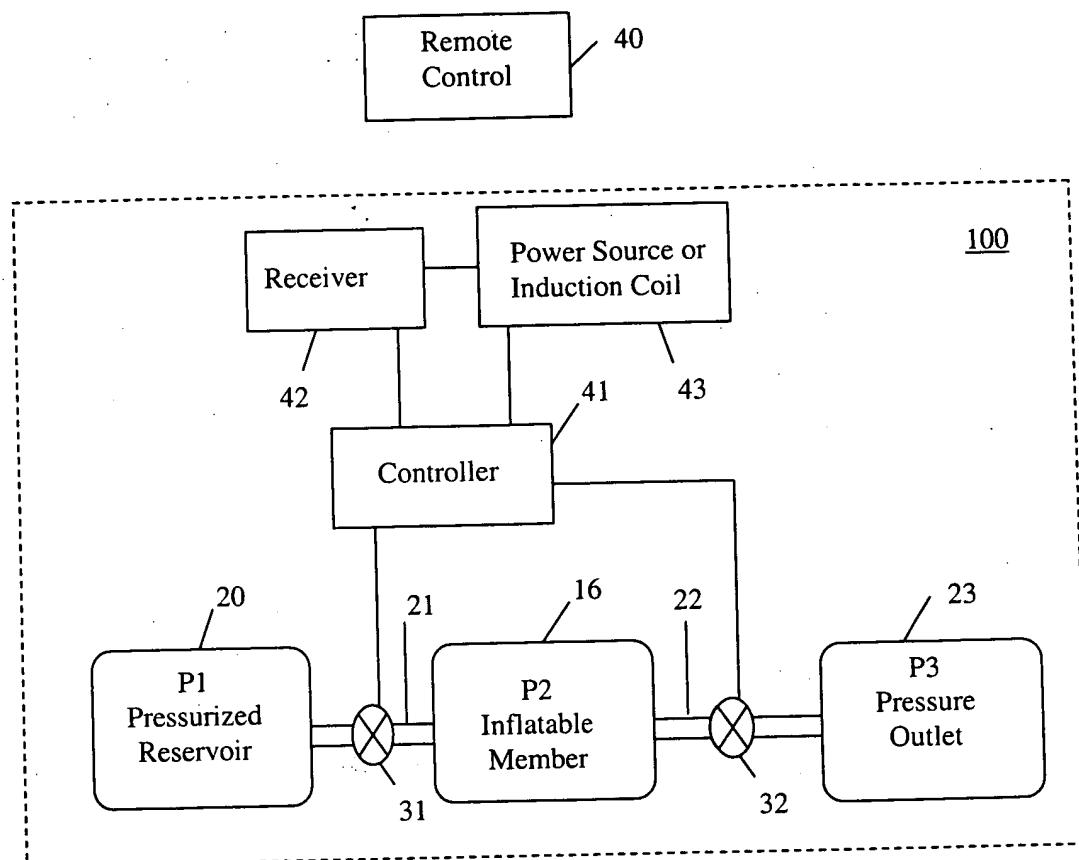


Fig. 3